March 18, 1999

The Honorable Dan Burton, Chairman House Government Reform and Oversight Committee c/o Milt Copulos/Beth Clay Room 2157 RHOB Washington DC 20515 3602 '98 SEP 17 P12:20

Dear Congressman Burton:

Attached is the signed copy of a form letter appearing in the April 1999 issue of *Life Extension*. It is my opinion that the issues raised have a great deal of merit, and I'm pleased to be able to sign the letter.

The matter of dosage limits for sensitive individuals is brought up, and I wish to emphasize that even antibiotics may adversely affect a few sensitive individuals – e.g., penicillin. This of course is why the doctor asks us if we have any known allergic reactions to the medicines to be administered. And if unknown, keeps a close check upon us afterwards.

It is my belief that the FDA for instance is an opponent of what we call alternative medicine, or complementary and alternative medicine, now referred to as CAM. In fact, the practices of alternative medicine have been sanctioned by no less than the federal government with the creation of NCCAM, the National Center for Complementary and Alternative Medicine, within the NIH.

There is the notion in fact that CAM is the wave of the future, and my own leanings are best expressed in terms of the enclosed announcement for Cancer and the Search for Selective Biochemical Inhibitors, to be released this month. (The publisher, CRC Press, is part of the Times Mirror Company.) Dosage levels of substances which may act selectively as inhibitors for cancer cell metabolism – but which do not adversely affect normal cells – are a critical subject.

Sincerely yours,

E.J. Hoffman

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FDA OVERSIGHT HEARING ON CODEX BADLY NEEDED

The Honorable Dan Burton, Chairman House Government Reform and Oversight Committee c/o Milt Copulos/Beth Clay Room 2157 RHOB Washington, DC 20515

Dear Congressman Burton:

Prior to last September's meeting of the Codex Committee on Nutrition and Food for Special Dietary Use, you and four other members of Congress strongly requested in writing that the FDA's Dr. Yetley remove the second paragraph from the U.S. codex comments on agenda item #5 (vitamins and minerals), because it contradicted the first paragraph, and lent credence to the unscientific notion that "maximum upper potency limits" should be put on vitamins and minerals. Dr. Yetley not only ignored your written request, but John Hammell caught her doing so on videotape which has been put on the Life Extension Foundation's website in the political section, along with footage of John being forced to stop taping by the German Codex Chairman (http://www.lef.org). A complete account of what happened is available at http://www.iahf.com under "breaking news."

From a standpoint of safety, there is no justification for attempting to apply a "Risk Assessment" document which was designed for evaluating toxic pharmaceutical drugs, to dietary supplements, which have been well established through the National Association of Poison Control Centers, and numerous other sources to be extraordinarily safe, even when consumed in doses much higher than the RDA. Orthomolecular physicians such as Bonnie Camo, M.D. have seen doses as high as 3 grams per day of niacin used in complete safety, while the National Academy of Sciences and FDA are advocating a maximum upper potency limit of just 35 mg, just because a few highly sensitive individuals experience a tingling sensation known as the "niacin flush" when taking niacin in low doses. There is nothing unsafe about the niacin flush, which actually helps circulation and is considered pleasurable by some.

It is obvious to consumers around the world that the FDA is attempting to use the highly unscientific, and heavily prejudiced National Academy of Sciences document titled "A Risk Assessment Model for Establishing Upper Limits for Nutrients" as a means of moving beyond the consumer generated impasse at the Codex Committee on Nutrition and Foods for Special Dietary Use. The FDA has announced its intention to harmonize its regulations to emerging Codex standards in an Advance Notice of Proposed Rulemaking that was published in the Federal Register on July 7, 1997, vol. 62, #129 pp.36243-36248. You can view this at http://iahf.com/codx-fda.txt.

I urge you to call John Hammell, Bonnie Camo M.D., and other witnesses to a Hearing before your Committee, and I urge you to force the FDA to withdraw the second paragraph of its comments along with the NAS Risk Assessment document in keeping with current US Law. Congress has spoken clearly on this with the passage of DSHEA, and most recently again in October of 1997 when dietary supplements were specifically exempted from the harmonization language in the FDA Reform Bill.

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